Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

January 20, 2004

Dear Ladies and Gentlemen:

The Almond Board of California (ABC) wishes to submit comments in response to the questions posed in the Federal Register Notice dated November 25, 2003 (Docket number 2003N-0496, Food Labeling: Health Claims; Dietary Guidance).

On July 23, 2003 the FDA issued a final rule on a qualified health claim for nuts and heart disease based on a review of the current body of scientific research. Nut research, almond in particular, continues to evolve providing greater substantiation of a heart health benefit. Almond research has been published in leading peer-reviewed journals including *JAMA* and *Circulation: Journal of the American Heart Association.*

For your consideration, ABC submits the following comments on the process, future course of action and consumer education challenges regarding health claims. The comments have been divided by heading (Roman numeral), section (letter) and subsection (underlined) to coincide with the sections of the Federal Register notice.

II. Health Claims

A. Regulatory Alternatives for the Qualified Health Claim

Option 1- incorporate the interim procedures and evidence-based ranking system into a regulation under notice-and-comment rulemaking

The primary regulatory position for the FDA should be to maintain the integrity and original intent of the Nutrition Labeling and Education Act of 1990 (NLEA). NLEA was designed to provide information to the public about the food choices they make in a way that is truthful and not misleading. Additionally, NLEA established standards for protecting consumers from claims that could potentially harm them. Option 1 of the qualified health claims regulatory process (henceforth referred to as the process) provides a standard that would maintain the pre-market clearance of claims and thus protect the truest intent of NLEA.

Additionally, Option 1 proposes an expedient and yet thorough process for reviewing claims. This not only improves the efficiency of the FDA but also permits the food industry to exercise their First Amendment right of free speech in a timely fashion. Time limitations on free speech may effectually deny that freedom. Furthermore, Option 1 permits an exchange of ideas from the public through a comment period that we feel is valuable to the FDA by providing insight into public perception and understanding and to the industry by delivering a clearer understanding of consumer needs and wants.

2003N-0496

C4

Finally, Option 1 provides for a revision of a qualified claim given the advent of new research demonstrating a stronger or weaker relationship. This function becomes particularly relevant as the science evolves to demonstrate that a health claim is more substantiated than was first recognized by FDA. Allowing for revisions to existing claims in a timely fashion ensures that consumers will have the best information with which to make food choices and protect consumers from erroneous claims.

In sum, we support Option 1 as the process FDA should adopt for reviewing and regulating qualified health claims for the reasons provided above.

Related to erroneous claims and consumer safety, we would like to offer additional comments regarding the current health claims ranking system (A through D). Whereas we recognize that an A claim is synonymous with an unqualified health claim and that B level claims are represented by the body of science suggesting that a substantiated relationship exists, we are concerned about C and D level claims. The C and D level claims do not have or have very little evidence to support the relationship between a substance and the condition nor has the scant evidence "supporting" C and D claims been reproduced in numerous studies such as is the standard for A and B level claims. Therefore, C and D level claims may pose a threat to consumer safety if FDA permits foods to carry said claims even with the qualifying language.

We recommend that FDA revise the current system to only permit A and B level claims, claims that have well-documented supporting scientific evidence. This ensures that the communications and consumer perception of the claims available on labels and marketing materials are accurate and represent sound science. Consumers may draw conclusions above and beyond the actual qualifying language to C and D claims thereby giving these claims more credibility than is appropriate. C and D claims may also undercut the substantiation that A and B level claims require.

Option 2- reinterpret the SSA standard to apply to the accuracy of the characterization of the evidence supporting the claim, instead of the underlying substance-disease relationship and subject qualified health claims to notice-and-comment rulemaking.
It is our position that Option 2 defines a process that would be cumbersome and would not allow for the claim to evolve with the science. Option 2 would require a period of comment-and-rulemaking, a procedure that would take considerable time and could undermine the efficacy of the claim within the context of evolving science.

Furthermore, the process would impede evolution of claims based on new science. This would deny consumers expedient access to the most current body of research and would also subject them to undue risk if the evolving science determines that the claim is in fact untruthful and misleading as well as potentially harmful. Adopting this option would create barriers for the industry to communicate freely with consumers as protected by the First Amendment. We concur with the FDA that the value of commercial speech is the timeliness with which it is accomplished. Consumers have the right to complete and expedient access to the science and the industry has the right to communicate the potential health benefits while the issue is relevant as long as it is not false or misleading.

Additionally, Option 2 requires redefinition of the SSA standard and in effect, weakens FDA's position as an authoritative decision maker. Recanting the interpretation of SSA by FDA would provide room for criticizing FDA as fickle and wavering. Moreover, it would undermine unqualified claims that have been approved based upon the SSA standard.

For the reasons outlined above, we do not support Option 2 for the process.

Option 3- Treat qualified health claims as wholly outside the NLEA and regulate them solely on a post-market basis, if they are false or misleading.
It is our opinion that Option 3 is potentially harmful for the consumer and the industry. Allowing claims on a post-market basis would in effect incapacitate FDA from responding since their subpoena authority although strong in some areas of their jurisdiction is weak in the regulation for food and supplement labeling. Therefore, claims could be made that are not truthful and misleading thereby potentially causing harm to the consumer.

Adopting this procedure would also undercut industry members who have spent time and resources to substantiate claims through research. The Almond Board of California has conducted research for more than 10 years to demonstrate the relationship between almonds and reduced risk of heart disease through lowered total and LDL cholesterol. This research has been published in top peer-reviewed journals such as the *Journal of the American Medical Association* and *Circulation: Journal of the American Heart Association.* The qualified claim for nuts, therefore, is based on sound research. A post-market claim about nuts and a health condition that is not supported by research could undercut the well-documented qualified claim for nuts, such as almonds.

As a result, we do not support Option 3 as a definition for the process.

B. Issues raised in the Task Force Report

1. Data and Research on a Substance/Disease Relationship, including Incentive for SSA
In order to develop the data and research needed to substantiate the substance/disease relationship, the FDA should adopt a practice of meeting with manufacturers and clearly specifying the research FDA believes is necessary to achieve the SSA standard. This would remove a barrier to conducting research by enabling industry to target their research. Also, FDA should consider providing matching dollars or help obtain matching dollars from other governmental agencies to share in the investment into the research needed since this research would also be consistent with the educational spirit of NLEA for which FDA is responsible.

Finally, we encourage FDA to move away from an exclusive reductionist perspective and embrace food synergy. Comments from the FDA regarding nuts have noted that the mechanism e.g. the substance in nuts that exerts the health effect is unclear. However, research in various areas of food and nutrition suggests that nutrients in food work in

concert or synergistically to produce a particular effect. Requesting that foods be broken down into their individual components in order to qualify for a claim disregards the current understanding about how food exerts a health benefit. For example, almonds contain monounsaturated fat, dietary fiber), vitamin E, phytosterols and polyphenols. Which of these components is responsible for lowering cholesterol or reducing the risk of heart disease? Individually, these components do not perform as vigorously as the whole almond. Based on more than 10 years of almond research, it appears to be synergy of these individual substances that produces the heart health effect.

Therefore, we encourage FDA to broaden their acceptance of research to include whole food research that does not specifically identify one or two specific causative components.

2. Revised Claim Language for Unqualified Health Claims

The Almond Board of California agrees with FDA's assertion that the word "may" could potentially be misconstrued as some level of uncertainty regarding the evidence supporting the scientific relationship of a substance with a disease. If health claims are intended to describe the relationship between a substance and a disease and that relationship meets the SSA standard, than the word "may" should be excluded from the claim. We would additionally suggest that FDA conduct consumer research to ensure that in fact consumers understand the unqualified health claim without the word "may."

3. Interim final rules for Unqualified Health Claims

Interim Final Rules (IFR) permit a free exchange of ideas and commentary through publication in the Federal Register. Additionally, IFR allows FDA to conduct a review of the research and present that review to the public without intervening and potentially derailing discussions with interest groups whose position is inconsistent with the general public.

Concerning the FDA's wariness of a process that is not thorough, applying Option 1 above will allow revisions in claims as the research evolves. Essentially, under the Option 1 model, the FDA could appropriately apply IFR while assuring flexibility to revisit claims to ensure validity and veracity of the claims.

4. Use of Phrases Such as "FDA authorized" in Qualified and Unqualified Health Claims

The Almond Board conducted research into the consumer perception of the FDA authorizing a claim. The research found that 76 percent of consumers would believe a qualified health claim if it came from the FDA. The same percent of consumers would believe the claim if they heard it from their physician. In our eyes, this indicates that "FDA authorized" or "FDA approved" would be perceived as significant and credible for the consumer. However, we believe that in order to protect the credibility of the FDA, "FDA authorized" should only be used with A and B claims and ***not*** with C and D level claims for reasons previously addressed.

5. Consumer Education

As per our comments above regarding the ranking system for qualified health claims, we believe that the FDA would best serve the consumer by preserving A and B level claims while discontinuing C and D level claims. Again, this action would serve to reduce confusion and misleading communications.

6. Evaluations by Outside Scientific Groups

The Almond Board of California has often convened panels of experts to review almond research in order to further guide our research and communications approach. This is most helpful in identifying research gaps and to characterize the amount and type of additional research needed to draw conclusions about health relationships. These advisory committees or panels are comprised of top experts in the relevant topic areas who may be affiliated with a leading academic institution or governmental agency.

It is our opinion that the mere fact that a group of experts is convened outside of the FDA should be of no consequence as long as the members are recognized experts in their field. It should be the role of the industry to document expert credibility should FDA request such notification.

FDA should outline their expectations of the group process and deliverables so that panels can be designed to deliver what FDA requires rather than a trial-and-error process that will ultimately frustrate the industry and experts. Permitting and even encouraging industry to form such scientific groups would alleviate the burden on FDA and would in effect create a freer exchange of research and information with FDA.

7. Competent and Reliable Scientific Evidence

Echoing our earlier position that qualified claims should have scientific evidence to support the claim, we similarly feel that the current definition of "competent and reliable scientific evidence" is appropriate to set standards that would require tests, research and conclusions that are ultimately reviewed by content experts in a way consistent with best practices. This ensures competence of the science.

To the point of reliability, we believe that the results must be reproduced in subsequent studies in order to be reliable and therefore a body of science must exist in order to support the claim. We believe that this characterization of reliable is critical for properly determining the ranking of a health claim.

We also believe that this should be an "and" not an "or" statement so that both criteria—competent and reliable—must be met.

Therefore, we do not believe that this standard of "competent and reliable scientific evidence" could apply to a C or D claim when these claims by definition have very little to no evidence to substantiate a competent research approach or reliable evidence.

C. Issues for Future Consideration

Definition of Substance

The Almond Board would like to encourage FDA to broaden its definition of substance. As we noted earlier, more food-based research is finding that individual food substances (i.e., fiber, vitamin C, vitamin E) do not have the same effects on health, as do whole foods. This is true for almonds.

FDA requires that a substance be the subject of health claims. However, as far as almonds and cholesterol lowering (heart heath) is concerned, more than 10 years of research is supporting a total package or synergy mechanism. We are asking FDA to broaden the definition for substances when the research is unable to define a particular component in a food that is exerting the health benefit and when the research supports a synergy mechanism.

As for existing health claims, we believe that it is important for consumers to be able to make food choices that promote health and not necessarily to become nutrition experts. We, therefore, believe that "food-specific" health claims (i.e., almonds, yogurt) rather than the "substance-specific" claims (i.e., calcium) are more useful for consumers. It is unrealistic to expect consumers to acquire technical nutrition knowledge to make healthful food choices.

Refining the processes and procedures of health claims approval and regulation will ultimately enable consumers to make healthful lifestyle decisions. We appreciate that the FDA has taken the time to solicit comment from the public and look forward to future dialogue with the agency.

Respectfully Submitted,

Karen Lapsley

Stacey Kollmeyer

Karen Lapsley, ScD
Director of Scientific Affairs
Almond Board of California

Stacey Kollmeyer
Senior Manager Communications
Almond Board of California